05-15-06

AF/1617
TJW

PTO/SB/21 (09-04)
Approved for use through 07/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Total Number of Papers in This Submission: **One**

Application Number	**09/872,250**
Filing Date	**June 1, 2001**
First Named Inventor	**Gary S. Grubb**
Art Unit	**1617**
Examiner Name	**San Ming R. Hui**
Attorney Docket Number	**WYTH0106-100 (AM100058)**

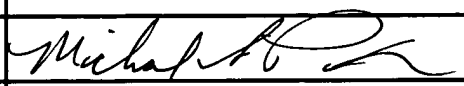
ENCLOSURES *(check all that apply)*

- ☐ Fee Transmittal Form
  - ☐ Fee Attached
- ☐ Amendment/Reply
  - ☐ After Final
  - ☐ Affidavits/declaration(s)
- ☐ Extension of Time Request
- ☐ Express Abandonment Request
- ☐ Information Disclosure Statement
- ☐ Certified Copy of Priority Document(s)
- ☐ Reply to Missing Parts/ Incomplete Application
  - ☐ Reply to Missing Parts under 37 CFR1.52 or 1.53
- ☐ Drawing(s)
- ☐ Licensing-related Papers
- ☐ Petition
- ☐ Petition to Convert to a Provisional Application
- ☐ Power of Attorney, Revocation Change of Correspondence Address
- ☐ Terminal Disclaimer
- ☐ Request for Refund
- ☐ CD, Number of CD(s) ____
  - ☐ Landscape Table on CD
- ☐ After Allowance Communication to TC
- ☐ Appeal Communication to Board of Appeals and Interferences
- ☐ Appeal Communication to TC **(Appeal Notice, Brief, Reply Brief)**
- ☐ Proprietary Information
- ☐ Status Letter
- ☒ Other Enclosure(s) *(please identify below)*:
  - **Appellant's Revised Brief Pursuant to 37 C.F.R. § 41.31 dated May 12, 2006**
  - **with Claim Appendix**
  - **Evidence Appendix - None**
  - **Related Proceedings Appendix - None**

Remarks

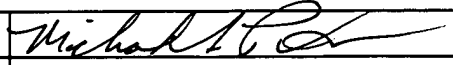
EXPRESS MAIL LABEL NO.: EV552 953 540US
DATE OF DEPOSIT: May 12, 2006

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm	**Cozen O'Connor, P.C.**		
Signature			
Printed Name	**Michael A. Patané**		
Date	**May 12, 2006**	Reg. No.	**42,982**

CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being deposited, via Express Mail Service, with the United States Postal Service with sufficient postage in an envelope addressed to: Mail Stop Appeal Brief-Patents, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below.

Signature			
Typed or printed name	**Michael A. Patané**	Date	**May 12, 2006**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:	Gary S. Grubb	**Art Unit:**	1617
		Examiner:	San Ming R Hui
Serial No.:	09/872,250	**Confirmation No.:**	4735
Filed:	June 1, 2001	**Docket No.:**	WYTH0106-100 (AM100058)
For:	**STARTER KIT FOR LOW DOSE ORAL CONTRACEPTIVES**		

MAIL STOP APPEAL BRIEF-PATENTS
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

VIA EXPRESS MAIL LABEL NO: EV552 953 540US
DATE SENT: May 12, 2006

APPELLANT'S REVISED BRIEF PURSUANT TO 37 C.F.R. § 41.31

This Revised Brief is being filed in response to the Notification of Non-Compliant Appeal Brief mailed on April 12, 2006. Appellants respectfully submit that this brief complies with 37 C.F.R. § 41.37. Appellants appeal the Final Rejection dated September 14, 2005 in connection with the above-identified application. No Advisory Action has been received. A Notice of Appeal with appropriate fees was filed on November 9, 2005. This brief contains the items required by 37 C.F.R. § 41.37, under appropriate headings, and an authorization to charge the fee set forth in 37 C.F.R. § 41.20(b)(2).

CONTENTS

(i) Real Party in Interest

The real party in interest is Wyeth, the sole Assignee of all right, title and interest in the above-referenced application, as evidenced by the Change of Name documents recorded August 3, 2005 at reel 016608 and frame 0507 indicating a change of name from AMERICAN HOME PRODUCTS CORPORATION to WYETH and the Assignment to AMERICAN HOME PRODUCTS CORPORATION executed by all inventors and recorded on June 6, 2001 at reel 011888 and frame 0500 of the USPTO records.

(ii) Related Appeals and Interferences

No other appeals or interferences are known to appellant, appellant's legal representative, or assignee which would directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(iii) Status of Claims

Claims 1-11 are pending in the application; each has been rejected under 35 U.S.C. § 103 over a combination of J. Endikrat *et al.*, *A Twelve-Month Comparative Clinical Investigation of Two Low-Dose Oral Contraceptives Containing 20 µg Ethinylestradiol/75µg Gestodene and 30µg Ethinylestradiol/75µg Gestodene with Respect to Efficacy, Cycle Control, and Tolerance*, Contraception, 1997, 55:131-137 (Endikrat *et al.*); U.S. Patent No. 5,552,394 (Hodgen '394), and Basic & Clinical Pharmacology, Ed. B.G. Katzung, 6th Ed., p. 620 (Katzung).

(iv) Status of Amendments

No amendment to the claims has been made at any time during the prosecution of this application. All claims are original.

(v) Summary Of Claimed Subject Matter

Claim 1 is the sole independent claim; it is original and has never been amended. For convenience, it is reproduced here:

> 1.(Original) An oral contraceptive starter kit comprising at least two cycle packs of oral contraceptives containing an estrogen and a progestin, and having a penultimate and a last cycle pack, the effective dosage of steroid in the penultimate cycle pack being greater than the effective dosage of steroid in the last cycle pack, the last cycle pack providing no more than about 20 µg estrogen per dosage unit.

The claimed invention is described below with reference to page and line numbers of the specification as originally filed. Additional support is also found in the various examples spanning specification pages 4 through 10.

The claimed invention relates to a multi-cycle starter kit for oral contraceptives. (p. 2, ln. 3-4.) The kit contains an oral contraceptive pack for each of at least two separate menstrual cycles. (p. 2, ln. 3-5; p.4, ln. 10-14.) Each oral contraceptive pack contains individual doses of oral contraceptive or a placebo/non-estrogenic agent, as is common in the art, for each day of the menstrual cycle. (p. 2, ln. 15; p2, ln. 17-23.) Each contraceptive dose contains both an estrogen and a progestin. (p.2, ln. 5; p2, ln. 17-23; p. 2, ln. 30.) In order to reduce undesirable spotting and breakthrough bleeding, which is more common in the initial cycle or cycles, (p.2, ln. 8-11) the starter kit includes at least one initial cycle pack (the penultimate pack) which includes daily doses containing a greater amount of steroid (estrogen) than found in the last pack (p.3, ln. 19; original claim 1). The last pack contains individual daily doses not exceeding 20 µg estrogen. (p. 2, ln. 7-8; original claim 1.) The low dose in the last cycle pack is sufficient to produce the desired contraceptive effect without the potential risks that might be associated with higher doses of estrogen. (p. 2, ln. 14-15.) This low dose or a lower dose is continued after the starter kit has been used completely. (p. 2, ln. 14-15.) Thus, Appellants' claimed kit provides higher doses of steroid in the initial cycle(s), where increased incidence of spotting and bleed through is expected, followed by reduced steroid levels in subsequent cycles, where lower incidence of spotting and breakthrough bleeding is expected.(p. 2, ln. 3-15; p. 3, ln. 17-19).

(vi) Grounds Of Rejection To Be Reviewed On Appeal

The sole issue before the Board is whether claims 1-11 are unpatentable under 35 U.S.C. § 103 over the combination of Endikrat *et al.*, Hodgen '394, and Katzung.

(vii) Argument

Claims 1-11 stand rejected for alleged obviousness under 35 U.S.C. § 103 (a) over Endikrat *et al.*, Hodgen '394, and Katzung.

A. The Claimed Invention

Independent claim 1 is reproduced here as representative of the invention:

> 1. An oral contraceptive starter kit comprising at least two cycle packs of oral contraceptives containing an estrogen and a progestin, and having a penultimate and a last cycle pack, the effective dosage of steroid in the penultimate cycle pack being greater than the effective dosage of steroid in the last cycle pack, the last cycle pack providing no more than about 20 µg estrogen per dosage unit.

A complete listing of the claims is attached below as the Claims Appendix.

B. The Rejection

The Action states it "would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the oral contraceptives packs of 30 mcg and 20mcg of Ethinylestradiol together in a kit." (see Office Action, p. 3.) Appellants note the Action's clear admission that the "primary references do not expressly teach the combination of the oral contraceptives packs together as a kit" (see Office Action, p. 3). The Action also notes that Hodgen '394 teaches "a method of reducing breakthrough bleeding in the menstrual cycles except for the first cycle employing ultra-low dose of Ethinylestradiol" (see Office Action, p. 2, emphasis added). The Action also indicates that Katzung is relied upon merely because it provides a list of suitable progestins for use in contraceptives (see Office Action, p. 3). Thus, to reach Appellants' claimed invention of a starter kit comprising at least two cycle packs wherein the last cycle pack contains less steroid than earlier cycle packs and no more than about 20µg estrogen per dosage unit, the Office relies on Endikrat *et al.*

C. The Cited Art

Endikrat *et al.* shows two separately administered treatment regimes. Each involves a treatment regime which was tracked for twelve cycles. In the first regime, patients were administered a contraceptive containing 20µg ethinylestradiol (EE), through each of the twelve cycles. Under the second regime, patients were administered a contraceptive containing 30µg

EE through each of the twelve cycles. The purpose of the study was to compare effectiveness, tolerability, and cycle control offered by the favored lower 20µg dose when compared to the 30µg dose. Effectiveness, tolerability, and cycle control were found to be sufficient with the 20µg regime. Endikrat *et al.* conclude "following the trend to further reduce hormone dose, the 20 µg EE2 oral contraceptive could be administered in the first line." (p. 136.)

Hodgen '394 supports the use of ultra-low dose ethinylestradiol throughout the treatment regime, even in initial cycles, despite higher bleeding rates in initial cycles. The disclosure of Hodgen '394 compares the administration of ***consistent*** low doses of oral contraceptives over three consecutive 28 day cycles, where one test group is administered the oral contraceptive for 21 days of each 28 day cycle and a second test group is administered the oral contraceptive for 24 days of each 28 day cycle; on the remaining days a placebo was given. As with Endikrat *et al.*, the initial cycle revealed greater incidence of spotting and breakthrough bleeding in both groups. In subsequent cycles, where the oral contraceptive dose was consistent with the initial cycle, lower levels of breakthrough bleeding and spotting were seen in both groups compared to the initial cycle. Lower levels were seen in subsequent cycles of the 24 day treatment cycle when compared to the 21 day treatment cycle. Hodgen '394 teaches that the longer 24 day treatment regime results in lower breakthrough bleeding and spotting levels, ***after*** the initial cycle. (see Abstract, and col. 6, lines 35-40.) At no time were any test subjects from either group switched from a relatively high dose to a relatively low dose; the dose was consistent from cycle to cycle. Hodgen '394, like Endikrat *et al.*, notes the desire to reduce the overall hormonal intake indicating that even with the longer 24 day treatment cycle, the lower daily dose still provides a significant reduction in hormone intake over an annual treatment period. (Col. 5, lines 55-60) Hodgen '394 is silent with respect to altering the dose in any way from one cycle to the next. Indeed Hodgen '394 reports and apparently accepts the "reduced incidence of breakthrough bleeding after the first cycle." (see Hodgen '394 Abstract, emphasis added.)

Hodgen '394 and Endikrat *et al.* have several things in common. Most importantly is that in each case, in each study, each patient was administered an oral contraceptive from one cycle to the next having an identical content as the oral contraceptive administered in the first month and every month thereafter during the treatment. Both recognize that with low dose treatment, the initial treatment cycles, and particularly the first cycle, suffer from relatively high incidence of spotting and breakthrough bleeding. Both also appear to agree that despite this problem, the benefits of the low dose treatment outweigh the problem, in light of the overall acceptable levels of spotting and breakthrough bleeding, tolerance, cycle control, and contraceptive efficacy.

D. The obviousness rejection should be withdrawn because 1. there is no motivation to modify or combine the references, 2. Appellants' claimed invention departs from conventional wisdom, 3. the rejection relies on impermissible hindsight, and 4. secondary considerations support the finding of non-obviousness.

Where a single prior art reference does not anticipate a claim under 35 U.S.C. § 102, it may be modified or combined with other prior art reference(s) to show obviousness under 35 U.S.C. § 103.

1. References may be modified or combined only where the art provides a suggestion or motivation to do so; such a suggestion or motivation is lacking in this case.

Section 103 requires that the modification or combination be obvious to those skilled in the art at the time of invention. The courts have repeatedly acknowledged the difficulty of this task, but have insisted upon showing a particular finding of a teaching, suggestion, or motivation to make the modification or combination in the prior art. The CAFC reiterated its longstanding position in *In re Dembiczak*, 175 F.3d 994, 999, 50 USPQ2d 1614, 1617 (Fed. Cir. 1999), noting that:

> Measuring a claimed invention against the standard established by section 103 requires the oft-difficult but critical step of casting the mind back to the time of invention, to consider the thinking of one of ordinary skill in the art, guided only by the prior art references and the then-accepted wisdom in the field.

"Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching or suggestion supporting the combination." *ACS Hosp. Sys., Inc. v. Montefiore Hosp.*, 732 F.2d 1572, 1577, 221 USPQ 929, 933 (Fed. Cir. 1984).

a) Both Endikrat *et al.* and Hodgen '394 are silent with respect to altering estrogen dose from one cycle to the next, as claimed by Appellants.

Appellants claimed starter kit claims a penultimate cycle pack having a greater steroid content than a last pack where the estrogen dose is 20μg or less. Thus, Appellants claim a kit where estrogen doses are altered from one cycle to the next.

"When a rejection depends on a combination of prior art references, there must be some teaching, suggestion, or motivation to combine the references. *In re Rouffet*, 149 F.3d 1350,

1355, 47 USPQ2d 1453, 1456 (Fed. Cir. 1998) (*citing In re Geiger*, 815, F.2d 686, 688, 2 USPQ2d 1276, 1278 (Fed. Cir. 1987)).

Neither Endikrat *et al.* nor Hodgen '394 disclose such regimes. Endikrat *et al.* discloses two separate treatment regimes, each maintaining either 20µg or 30µg consistently throughout the 12 month treatment period. Hodgen '394 also discloses two treatment regimes. In Hodgen '394, each treatment contains an identical dose (between regimes and from cycle to cycle). The difference between regimes is that in one treatment, estrogen is administered for 24 days, while in the other estrogen is administered for only 21 days. Thus, both Endikrat *et al.* and Hodgen '394, through the four disclosed treatment regimes, teach only the consistent dosing from one cycle to the next, even when looking at initial cycles compared to subsequent cycles. There simply is no teaching or suggestion to alter the dose from one cycle to the next as taught by Appellants, and no suggestion that it would be desirable to do so (except for *increasing* the dose where the low dose is ineffective).

For this reason alone, the obviousness rejection should be withdrawn.

b) Endikrat *et al.* and Hodgen '394 are silent with regard to any benefit of an initially higher estrogen dose, as taught by Appellants.

It was well known in the art that initial cycles under contraceptive treatment met with greater incidence of spotting, breakthrough bleeding, and other issues than in later cycles as the body adjusted to the treatment. The cited references recognize this fact and appear to view it as unchangeable or, at least, acceptable in light of other benefits. Each of the references is utterly silent with respect to addressing the increased incidence of spotting and breakthrough bleeding in initial cycles.

Not only must the prior art contain a teaching, suggestion or motivation to make the modification or combination, but the CAFC demands that the teaching, suggestion, or motivation be factually presented as evidence against the claimed invention. There must be evidence that "a skilled artisan, confronted with the same problems as the inventor and with no knowledge of the claimed invention, would select the elements from the cited prior art references for combination in the manner claimed." *In re Rouffet*, 149 F.3d at 1357, 47 USPQ2d at 1456; see also *In re Werner Kotzab*, 217 F.3d 1365, 1371, 55 USPQ2d 1313, 1317 (Fed. Cir. 2000) ("[A] rejection cannot be predicated on the mere identification . . . of individual components of claimed limitations. Rather, particular findings must be made as to the reason the skilled

artisan, with no knowledge of the claimed invention, would have selected these components for combination in the manner claimed.")

Neither Endikrat *et al.* nor Hodgen '394 recognizes the benefit of or purpose in varying the dose, except, in sharp contrast to Appellants' teachings, to *increase* the dose in subsequent cycles when the low dose treatment is insufficient or unacceptable. In fact, both, although confronted with the problem of initial breakthrough bleeding and spotting rates, appear to be focused on obtaining the lowest estrogen dose possible, without losing efficacy or cycle control. Both appear to view the initial bleed through rates as acceptable in light of the benefits of reduced estrogen intake. Without recognizing any benefit or purpose for using an initially higher estrogen dose, the references, alone or in combination, simply do not provide those of skill in the art with any motivation or suggestion to do so. Accordingly, the obviousness rejection should be withdrawn.

c) Unlike Appellants, neither Endikrat *et al.* nor Hodgen '394 address the problem of initial breakthrough bleeding and spotting and, therefore, do not suggest the desirability of any change to do so.

Despite higher incidence of spotting and breakthrough bleeding in initial cycles, Endikrat *et al.* and Hodgen '394 are each satisfied that their disclosed low dose regimes are acceptable and suitable for use as contraceptive treatments. Endikrat *et al.* is particularly relevant on this point, since it discloses both a relatively high dose treatment and a low dose treatment.

"When determining the patentability of a claimed invention which combines two known elements, 'the question is whether there is something in the prior art as a whole to suggest the desirability, and thus the obviousness, of making the combination.' " *In re Beattie*, 974 F.2d 1309, 1311-12, 24 USPQ2d 1040, 1042 (Fed. Cir. 1992) (*quoting Lindemann*, 730 F.2d at 1462, 221 USPQ at 488).

Endikrat *et al.* shows higher incidence of spotting and breakthrough bleeding in the initial cycles of both the 20 µg EE and the 30 µg EE treatment regimes when compared to subsequent cycles. The data presented in Endikrat *et al.* appear to show that the 20 µg EE treatment regime has greater incidence of any breakthrough bleeding in the first three months than the similar treatment period of the 30 µg EE treatment (see Fig. 1). Nevertheless, the reference does not indicate that this made the treatment unacceptable. Instead, it reports comparable drop-out rates in both the 20 µg and the 30µg study as well as similarities with regard to compliance and other factors. These factors suggest that patients responded equally to either

treatment regime and were not discouraged any more or less from continuing with either treatment when compared to the other. Thus, Endikrat *et al.* does not teach or suggest that the 20µg treatment was ineffective or undesirable. Endikrat *et al.* reports that the study indicates that the 20µg EE preparation is reliable and well-tolerated, showing only "slightly less favorable bleeding patterns". (p. 136, col. 1, third full paragraph.) The 20µg treatment "neither compromises contraceptive reliability nor leads to clinically unacceptable cycle control." Endikrat *et al.* continues, stating the

> potential advantage of the low hormone content might outweigh in part the less favorable bleeding pattern. Following the trend to further reduce the hormone dose, the 20 µg EE2 oral contraceptives could be administered in the first line. For women having a history of cycle control problems or for women having experienced such problems under a 20 µg EE2 preparation, preference should be given to the 30 µg EE2 drug.

Endikrat *et al.* therefore does not suggest to one of skill in the art the need or desire to alter the 20µg treatment regime, except to switch to higher doses in later cycles when necessary.

2. Appellants claimed invention breaks from the conventional wisdom followed in the applied art.

As noted, Endikrat *et al.* sets forth and follows the conventional wisdom to administer as low a dose as possible, and therefore suggests *beginning* treatment with a low dose and *increasing* it *only* when *necessary*--that is if control or bleeding problems persist beyond the initial cycle(s) where it is expected. This conventional wisdom is the ***exact opposite*** of the treatment regime facilitated by Appellants' claimed contraceptive kit. Proceeding contrary to accepted wisdom in the art is evidence of nonobviousness. *See* MPEP § 2145 X.D.3 *citing In re Hedges,* 783 F.2d 1038, 228 USPQ 685 (Fed. Cir. 1986).

Endikrat *et al.* follows the conventional wisdom, teaching away from treatment regimes and kits that facilitate administration of relatively high doses of steroid in initial cycles followed in subsequent cycles by relatively low dose administration, such as those in the claimed starter kit. In fact, Endikrat *et al.* ultimately concludes, despite the higher incidence of initial breakthrough bleeding, that prescription of the 20µg treatment should be the ***first line*** therapy, and only "in case of persistent cycle control problems, a switch to the 30µg EE2 drug should be considered." Thus, there is nothing in Endikrat *et al.* that would suggest the desirability of modifying the 20µg treatment regime as proposed by Appellants. The teaching of Endikrat *et al.* is clearly to ***begin***

all treatment regimes with the lower, 20μg EE dose. This is in sharp contrast to Appellants' teachings and claimed starter kit.

3. Only through impermissible hindsight, using Appellants' own teachings, can one find motivation to combine or modify the cited references to reach the claimed invention.

Reading Endikrat *et al.* in view of Appellants' specification and claims certainly supports Appellants' position that an initial relatively high dose (30μg EE) cycle followed by relatively low dose (20μg EE) cycles benefits the patient with reduced breakthrough bleeding and spotting during the initial cycles and reduced estrogen in later cycles without substantially sacrificing efficacy and control in later cycles. However, it is *only* through this impermissible hindsight, in full view of Appellants' disclosure, that one skilled in the art is given the suggestion to combine a relatively high dose initial treatment with a subsequent low dose treatment. No such suggestion is found in the art.

The case law makes it perfectly clear that the prior art, and not Appellants' disclosure, must provide the teaching, suggestion, or motivation to modify or combine prior art references. Modifying or "[c]ombining prior art references without evidence of such a suggestion, teaching, or motivation simply takes the inventor's disclosure as a blueprint for piecing together the prior art to defeat patentability–the essence of hindsight." *In re Dembiczak*, 175 F.3d at 999, 50 USPQ2d at 1617.

Each of Endikrat *et al.* and Hodgen '394 clearly teach only the conventional approach of administering identical doses from cycle to cycle, with preference being shown for starting with safer, low dose formulations. Indeed, Endikrat *et al.* set forth data, in a side by side comparison, showing the effects of the high and low dose treatment regimes over a twelve month period without recognizing or suggesting a combined treatment regime. In the end, Endikrat *et al.* conclude not that the two regimes should be combined, but rather that the low dose regime should be used wherever effective, and the higher dose should be used only after the low dose has been shown ineffective or intolerable in a particular patient. There simply is no recognition in Endikrat *et al.* that the two regimes could be combined for beneficial results. Nor is this recognition found in Hodgen '394. Only Appellants have suggested varying the dose from relatively higher dosage initial cycle to relatively lower dosage subsequent cycles. The case law is clear that Appellants' own teaching cannot be used as a blueprint for hindsight reconstruction. Accordingly, the obviousness rejection should be withdrawn.

4. Secondary considerations, such as long-felt, but unsolved need, are indicative of non-obviousness.

The Supreme Court has recognized several secondary considerations as indicative of non-obviousness in support of patentability. One of these secondary considerations is a long felt need in the art coupled with a prior failure to solve the problem. (*Graham v. John Deere*, 383 U.S. 1, 148 USPQ 459 (1966).)

Increased incidence of breakthrough bleeding and spotting in initial contraceptive treatment cycles has been recognized in the prior art, particularly since the introduction of so-called "low-dose" contraceptives. There has been a long-felt need in the art to address the problem, particularly in low dose formulations. This long-felt need has been accompanied by a failure to provide a solution. Until now, those of skill in the art, including Endikrat *et al.* and Hodgen '394, have described treatment regimes consistent from one cycle to the next and contented themselves with acceptable bleeding patterns that contain relatively higher incidence of breakthrough bleeding and spotting in initial treatment cycles. Appellants, for the first time, have addressed the problem and provided a viable solution. Such a long-felt need and failure to solve the problem are secondary considerations showing non-obviousness supporting the patentability of Appellants' claimed invention. Despite the existence of the data found in Endikrat *et al.*, neither the authors of that paper nor, as far as the record shows, anyone else save for Appellants, has suggested a combination therapy whereby initial cycles are treated with higher dose estrogen formulations followed in subsequent cycles with low dose estrogen formulations. Indeed, prior to Endikrat *et al.*, and since, the conventional wisdom has been to find a treatment that is well-tolerated and to continue with that treatment and dosage from one cycle to the next. Under this conventional wisdom, a patient started on a 30μg formulation that was well-tolerated would be maintained on that formulation unless some undesirable complications resulted. Even in that case, the treatment would be stopped, and reevaluated before starting a new treatment. Even if a new low dose contraceptive were prescribed at this point, it would not be in the form of Appellants' claimed starter kit, but rather as a new treatment regime administering only the newly prescribed low dose formulation.

Appellants respectfully submit that in light the above discussion, the Action does not set forth a *prima facie* case of obviousness, since there is no showing of any motivation in any of the references, that would lead one skilled in the art to modify the teachings of the references to result in a treatment regime and/or kit for facilitating the treatment regime, where the dose in the

initial cycle(s) is relatively high followed by relatively low doses in later cycles, as taught by Appellants.

Appellants respectfully assert that the obviousness rejection should be withdrawn since there is no motivation to modify or combine the references, Appellants' claimed invention departs from conventional wisdom, the rejection relies on impermissible hindsight, and secondary considerations support the finding of non-obviousness.

(viii) Claims Appendix

1.(Original) An oral contraceptive starter kit comprising at least two cycle packs of oral contraceptives containing an estrogen and a progestin, and having a penultimate and a last cycle pack, the effective dosage of steroid in the penultimate cycle pack being greater than the effective dosage of steroid in the last cycle pack, the last cycle pack providing no more than about 20 μg estrogen per dosage unit.

2. (Original) The starter kit of claim 1 wherein the cycle packs are packaged in individual units.

3. (Original) The starter kit of claim 1 wherein multiple cycle packs are packaged together as a single unit.

4. (Original) The starter kit of claim 1 further comprising written instructions describing the order of use of said cycle packs.

5. (Original) The starter kit of claim 1 wherein the estrogen is ethinylestradiol.

6. (Original) The starter kit of claim 1 wherein the progestin is selected from the group consisting of trimegestone, nomegestrol, norgestrel, levonorgestrol, cyproterone acetate, 3-ketodesogestrel, desogestrel, gestodene, drospirenone, medroxy progesterone acetate, megestrol acetate, norgestimate, 17B deactyl norgestimate, osaterone, norethindrone, norethindrone acetate, lynestrenol, norethynodrel, and ethynodiol diacetate.

7. (Original) The starter kit of claim 1 wherein the estrogen is ethinylestradiol and the progestin is levonorgestrel.

8. (Original) The starter kit of claim 1 wherein the estrogen is ethinylestradiol and the progestin is norethindrone.

9. (Original) The starter kit of claim 1 wherein the estrogen is ethinylestradiol and the progestin is norethindrone acetate.

10. (Original) The starter kit of claim 1 wherein the estrogen is ethinylestradiol and the progestin is gestodene.

11. (Original) The starter kit of claim 1 wherein the estrogen is ethinylestradiol and the progestin is norgestimate.

(ix) Evidence appendix

None.

(x) Related proceedings appendix.

None.

Conclusion

Appellants respectfully assert that independent claim 1 and all claims dependent therefrom are patentable over the cited combination of references. Withdrawal of the rejection is respectfully requested.

The Commissioner is hereby authorized to charge any fee or underpayment thereof or credit any overpayment to deposit account no. 50-1275.

Early and favorable action by the Board is respectfully requested.

Respectfully submitted,

COZEN O'CONNOR, P.C.

Date: May 12, 2006

By: Michael A. Patané
Reg. No. 42,982

1900 Market Street, 5th Floor
Philadelphia, PA 19103-3508
215-665-6966 - Telephone No.
215-701-2100 - Facsimile No.